

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Renée Marie Bumb,
District Court Judge

This Document Relates to All Actions

**DEFENDANT ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.'S
MEMORANDUM IN SUPPORT OF OBJECTIONS TO AND MOTION TO
REVERSE SPECIAL MASTER ORDER 100 GRANTING PLAINTIFFS'
MOTION FOR RULE 37 SANCTIONS**

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Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), by and through its undersigned counsel, hereby objects to Special Master Order 100 (“SMO 100”) (ECF No. [2778](#)) awarding adverse inference instructions under Rule 37.

In December 2021, Plaintiffs filed a motion seeking trial sanctions based on: (1) ZHP’s President Baohua Chen’s inability to be deposed in this case after being denied permission by the People’s Republic of China (the “Chinese government”) to travel out of the country for such a deposition; and (2) ZHP’s initial concerns about producing a relatively small number of documents subject to Chinese data privacy statutes, all of which were produced in 2022. On July 22, 2024, the Special Master authorized two “adverse” jury instructions in Plaintiffs’ favor, both of which would have the clear effect of substantially diluting Plaintiffs’ burden of proof with respect to a fundamental substantive issue in the case: whether ZHP was aware of the presence of nitrosamines in its valsartan active pharmaceutical ingredient (“API”) in 2017 and failed to disclose it.

SMO 100 authorizes jurors to “infer” that: (1) “Mr. Chen’s deposition testimony would have included information about ZHP’s” supposed “knowledge of the nitrosamine contamination” of the medication at issue; and (2) documents ZHP has allegedly withheld “would have been unfavorable to ZHP.” (SMO 100 at 11, 12.) Although the Special Master repeatedly highlighted the “permissive” nature of these two inferences, jurors would almost certainly draw the inference that these two

instructions invite them to reach, neither of which is based in either law or fact.

First, the evidence does not establish that ZHP engaged in sanctionable conduct. Even before Judge Kugler affirmed the Special Master’s ruling compelling Mr. Chen’s deposition in August 2021 (ECF No. [1475](#)), ZHP had initiated the process of seeking permission from the Chinese government to allow Mr. Chen to travel out of mainland China for his deposition, establishing ZHP’s reasonable and good-faith attempts to comply with the order. The fact that the Chinese government ultimately barred Mr. Chen from leaving the country demonstrates that any non-compliance with Judge Kugler’s discovery order was entirely the result of foreign law and foreign government action, which is a “weighty” reason for declining to impose sanctions. *See Societe Interationale Pour Participations Industrielles et Commerciales, S. A. v. Rogers*, 357 U.S. 197, 211-13 (1958) (reversing imposition of sanctions). While the Court inquired during the recent status conference about what efforts have been undertaken to secure Mr. Chen’s deposition “lately” (ECF No. [2791](#) (“July 23, 2024 Hr’g Tr.”) 154:2-6), Mr. Chen cannot file a new application for a travel permit without providing a new reason/purpose for foreign travel.

SMO 100 also misunderstands the relevant discovery record in finding that ZHP improperly failed to produce documents. ZHP produced the documents at issue to Plaintiffs by October 2022, 18 months before the sanctions order. While ZHP

initially objected to producing a number of the documents, primarily because they were subject to protection under Chinese data privacy laws, it produced the documents *at the risk of penalty under those foreign laws* and represented as much in a sworn certification provided to Plaintiffs in 2022 at the Special Master’s direction. The Special Master nonetheless suggested that ZHP is continuing to withhold: (1) a native version of a July 27, 2017 email written by a ZHP scientist about a different drug molecule known as irbesartan that has been produced as a PDF; and (2) “any [additional] drafts” of a report on irbesartan related to that email, a version of which has also already been produced. ZHP is not withholding any materials. ZHP’s counsel has certified under oath that ZHP has produced all non-privileged documents within its possession, and there is no basis for crediting Plaintiffs’ speculation that “more documents [or versions of documents] exist.” (ECF No. [2750](#), at 30-32.)

Second, the sanctions ordered by the Special Master would be unjust, even if ZHP had engaged in sanctionable conduct, because of their severity and because they are not sufficiently tied to the alleged misconduct. The Special Master sought to downplay the severity of the sanctions by labeling them as merely “permissive” in nature and highlighting the fact that he had denied more extreme “death penalty” punishments, such as striking ZHP’s defenses or deeming certain allegations admitted. (SMO 100, at 1-2.) This reasoning fundamentally misapprehends the

import of the two jury instructions, which would invite jurors to accept Plaintiffs' central theory of the case—that ZHP had prior "knowledge of the nitrosamine contamination of ZHP's Valsartan"—without requiring Plaintiffs to satisfy their burden of proof. (*Id.* at 20.) But Plaintiffs did not allege the sort of bad faith required for the harsh sanction of an adverse inference, and the adverse inferences would not "restore" Plaintiffs to the position they would have been in if Mr. Chen had been deposed. Mr. Chen would not have been able to provide any evidence related to ZHP's purported knowledge of nitrosamine impurities in the summer of 2017 because he was not a recipient of the July 2017 email, and there is no other evidence that he was aware of the nitrosamine-related issues it raised. In other words, SMO 100 would punish ZHP and reward Plaintiffs by telling the jury that one of Plaintiffs' central contentions is true, even though that contention is not tied to the allegedly missing discovery.

For all of these reasons, elaborated in greater detail below, and in ZHP's prior objections to SMO 98 (ECF Nos. [2738](#), 2767), which are incorporated herein by reference, the Court should sustain ZHP's objections to the Special Master's ruling and overrule it.

BACKGROUND

Throughout this multi-year MDL proceeding, Plaintiffs have obtained voluminous discovery from ZHP and its affiliates, including depositions of ten

corporate representatives and seven fact witnesses. (See ECF No. [1900](#), at 11.) In addition, ZHP and its affiliates have produced almost 400,000 documents totaling more than 3.5 million pages, which were collected from more than 90 custodians using more than 400 search terms identified by Plaintiffs. (*Id.* at 14 n.7.) Nonetheless, on December 30, 2021, Plaintiffs moved for sanctions under Rule 37, arguing that ZHP should be punished because: (1) the Chinese government refused to allow Mr. Chen to leave mainland China to provide a deposition in this litigation; and (2) ZHP allegedly failed to produce a relatively small number of documents that have now long been produced. (See generally ECF No. [1838-1](#).)

A. The Deposition of Baohua Chen

From the outset of this litigation, Plaintiffs knew that deposing Chinese citizens who reside in China would likely require permission from the Chinese government through certain procedures established under the Hague Convention and China's Civil Procedure Law. (See ECF No. [86](#) 16:3-6; ECF No. [579](#) 14:2, 21:11 (Court recognizing the "very sticky" and "amazingly complex" issues in securing depositions of Chinese nationals); ECF No. [565](#) 25:21-26:4 (ZHP counsel explaining that "Hague Convention protocols would apply").) Plaintiffs, however, never invoked the Hague Convention or sought approval from the Chinese government to depose ZHP witnesses living in China. (See ECF No. [610](#), at 37-38 ("Plaintiffs can—they certainly are permitted, they haven't made any attempt and, in fact, have

outright refused to make an attempt to obtain a letter of request to depose a witness in China”.) Nonetheless, to accommodate Plaintiffs’ request for corporate representative and individual fact witness depositions, ZHP facilitated the travel of 12 witnesses to Macao to provide remote deposition testimony, an arduous process that was further complicated by logistical and bureaucratic hurdles relating to the COVID-19 pandemic. (See ECF No. [1900](#), at 5 n.3.) These witnesses addressed close to 60 different topics, including, *inter alia*, testing of valsartan, quality assurance, communications with regulatory bodies and compliance with regulatory standards. (See ECF No. [703-1](#) (listing 30(b)(6) topics).)

On the heels of this substantial discovery, ZHP objected to Plaintiffs’ demand to depose its President, Mr. Chen, under the “apex” doctrine, explaining that Mr. Chen “**had no material involvement** in the valsartan manufacturing, testing, analytical, quality control, quality assurance, research and development, recall, regulatory and sales functions at issue in this litigation.” (ECF No. [1247-2](#), at 2-3 (emphasis added); *see also* ECF No. [1900-5](#) 364:5-14 (ZHP party witness testifying: “I don’t think [Mr. Chen] has any time for that”)). The Special Master rejected that argument, and Judge Kugler affirmed his decision on June 22, 2021, holding that “plaintiffs cannot know what Mr. Chen will say specifically about the API contamination and his role in it until he is deposed.” (ECF No. [1475](#), at 2.)

Even prior to Judge Kugler’s ruling, ZHP diligently began the process to

secure permission for Mr. Chen to cross the Chinese border and travel to Macao¹ so that he could be deposed if Judge Kugler affirmed the Special Master’s holding. (See ECF No. [1900-1](#) (“Lu Decl.”) ¶ 3.) Unlike the 12 other ZHP witnesses, Mr. Chen has various roles in the Chinese government and therefore is not permitted to travel outside of mainland China absent express approval from ZHP’s Communist Party Committee, the Taizhou Federation of Industry and Commerce, and the Taizhou Exit-Entry Administration of the Public Security Bureau. (*Id.* ¶ 14.) ZHP employee Sihan Lu took the following steps to secure the requisite government approval:

- Ms. Lu had “preliminary” discussions with the Taizhou Federation of Industry and Commerce regarding Mr. Chen’s application in early June 2021. (*Id.* ¶ 3.)
- Ms. Lu completed and submitted the required Approval Form for Leading Cadres to Leave China (border) for Private Purposes to ZHP’s Communist Party Committee on June 9, 2021. (*Id.* ¶¶ 4, 6.) That Committee granted Mr. Chen’s request the following day. (*Id.* ¶ 7.)
- On June 14, 2021, Ms. Lu submitted Mr. Chen’s application to the Taizhou Federation of Industry and Commerce. (*Id.* ¶ 8.)
- Ms. Lu subsequently followed up “from time to time on the application status.” (*Id.* ¶ 9.)
- On October 21, 2021, the Taizhou Federation of Industry and Commerce verbally notified ZHP that Mr. Chen’s request would not be granted. (*Id.* ¶ 10.)
- Ms. Lu held further discussions with the Taizhou Federation of Industry and Commerce “to determine if the restriction on Mr. Chen’s travel

¹ Macao is a Special Administrative Region with its own legal code where compliance with American discovery demands is legally permitted.

could be lifted or modified.” (*Id.* ¶ 11.) Those conversations were unsuccessful, with a written denial being delivered to ZHP on November 12, 2021. (*Id.* ¶ 12.)

- On January 19, 2022, Ms. Lu sought permission to publicly disclose the written denial, which was denied. (*Id.* ¶ 13.)

Despite ZHP’s efforts to facilitate Mr. Chen’s deposition—and without first attempting to meet and confer with ZHP—Plaintiffs moved for sanctions, accusing ZHP of bad faith and suggesting that Mr. Chen could have somehow forced the Chinese government to approve his travel request if he had wanted to attend the deposition. (*See* ECF No. [1838-1](#), at 16; ECF No. [2182](#) (“Sept. 8, 2022 Hr’g Tr.”) 28:14-16, 52:9-25.) While ZHP strongly disputed these claims (*see, e.g.*, Sept. 8, 2022 Hr’g Tr. 41:3-23), the Special Master stated that there “[s]hould . . . be a declaration of a witness, or something that is evidentiary in nature” addressing these points (*id.* 41:24-42:6). Accordingly, on October 13, 2022, ZHP submitted a declaration from Professor Jacques deLisle—Co-Director of the Center for Asian Law at the University of Pennsylvania (ECF No. [2175-2](#) (“deLisle Decl.”))—explaining why “[t]he efforts described in the Lu Declaration are consistent with known patterns of efforts by applicants seeking government approvals of various types in China.” (deLisle Decl. ¶ 27.) Professor deLisle further explained that “[t]he choice of wording on the Application Form, the non-inclusion of the Special Master’s ruling, and the rejection of the application are also consistent with, and may reflect, broader concerns that party and state authorities in China have expressed and

embedded in policies and rules.” (*Id.* ¶ 28.) For example, Professor deLisle noted that ZHP’s decision not to attach the Court order compelling Mr. Chen’s deposition to the application is consistent with the fact that a “request to exit mainland China to be deposed in litigation in a foreign court proceeding raises particular concerns about which a relatively sophisticated applicant might well worry (and, in turn, such an applicant would seek to avoid drawing attention to this purpose in a request for permission to travel).” (*Id.* ¶ 29.) In other words, including that information could have precisely the opposite effect of that intended: i.e., it could lead to denial of the application.

On May 4, 2023—nearly seven months after ZHP provided the declaration—the Special Master struck the declaration as untimely. (ECF No. [2371](#), at 5.)

B. Production of Documents

On April 27, 2021, Plaintiffs notified the Court that the parties had reached an impasse with respect to four narrow categories of documents that the Special Master ultimately ordered be produced: (1) the custodial file of Maggie Kong, Mr. Chen’s chief of staff; (2) an investigative report regarding alleged contamination of irbesartan, a *different* drug molecule from the valsartan API that is the basis of Plaintiffs’ claims; (3) all documents referencing “TC-201729,” the project name for a lab-scale study of irbesartan; and (4) all documents relating to the batch testing for nitrosamines referenced in a document bearing Bates Number PRINSTON0075797.

(*See generally* ECF No. [1753](#).) While ZHP initially could not produce some of the requested documents due to technical difficulties and/or the passage of China’s Data Security Law, ZHP “agreed to produce the Documents—at the risk of penalty under Chinese law” in February 2022. (ECF No. [1900](#), at 3; *see also id.* at 16 (ZHP informing Plaintiffs that it would produce all of the remaining requested documents despite failing to obtain permission to do so from the Chinese government).)

Plaintiffs nonetheless insisted eight months later at oral argument that ZHP had still not met its production obligations. At that point, the Special Master stated that “it would be appropriate” for ZHP to “certify that [it has] complied with Special Master Order 54” and that the “record should reflect” such a “certification”—i.e., that ZHP’s counsel “conducted a diligen[t] search and produced everything that [was] ordered to be produced that [ZHP] could find.” (Sept. 8, 2022 Hr’g Tr. 39:3-8.) On October 21, 2022, ZHP’s counsel provided Plaintiffs with such a certification that included, *inter alia*: (1) an attestation that counsel had personally investigated the steps taken to identify the whereabouts of the four categories of documents discussed in SMO 54; (2) a representation that counsel had confirmed that the searches were conducted in a manner consistent with the Rules; (3) identification by bates number of additional documents produced as a result of those searches; and (4) confirmation that no more additional responsive documents were available. (*See generally* ECF No. [2738-3](#) (“Bernardo Cert.”).)

C. Jinsheng Lin's July 27, 2017 Email

Throughout this litigation, Plaintiffs have claimed that the four categories of documents discussed above are relevant because they may shed light on a July 27, 2017 email sent by ZHP analyst Dr. Jinsheng Lin to some of his ZHP colleagues.

Dr. Lin's email—which was written in his native language of Chinese—addresses a hypothetical impurity in the lab-scale production of irbesartan, which (as previously noted), is a different drug molecule from the valsartan API at issue in this litigation. (See ECF No. [2604](#), at 4.) Different translations of this document exist, and Plaintiffs have taken the position that some of those translations show that Dr. Lin compared the hypothetical impurity in irbesartan to nitrosamine impurities found in valsartan. As a result, Plaintiffs assert that the email shows that “ZHP knew that its valsartan was contaminated with NDMA” as of 2017. (See, e.g., ECF No. [2569-2](#), at 1.) By contrast, ZHP’s corporate representative, Jucai Ge, who was an original recipient of the email, has testified that Dr. Lin’s email references a patent, which is attached to his email, that notes the potential for the formation of “Valsartan Impurity K,” a different nitrosated impurity that can form when deacylated valsartan (yet another drug molecule) is quenched with sodium nitrite. (See ECF No. [2569-5](#) at Ex. 30 110:6-22; ECF No. [2569-5](#) at Ex. 109.) As ZHP’s witnesses have noted, it was this substance—Valsartan Impurity K formed by the quenching of deacylated valsartan—that Dr. Lin was suggesting the irbesartan impurity resembled, not

NDMA formed during the manufacture of the valsartan API at issue in this litigation. (See ECF No. [2569-5](#) at Ex. 30 110:18-22.) Plaintiffs have never sought Dr. Lin's deposition. Judge Kugler expressly recognized, in denying Plaintiffs' motion for partial summary judgment against ZHP on their fraud claims, that the meaning and import of the July 27, 2017 email are factual questions for the jury to decide in resolving Plaintiffs' allegations. (See ECF No. [2694](#), at 52 & n.53.)

Mr. Chen was not a recipient of Dr. Lin's email. In addition, the individuals at ZHP who *did* receive the email made clear in their depositions that because the email pertained to science issues, it would not have been discussed with Mr. Chen in his role as President. (See, e.g., ECF No. [2663-27](#) at Ex. 1 96:5-21 (ZHP employee testifying that she did not inform Mr. Chen of Dr. Lin's July 27 email and that it would be her expectation that the issues discussed "would not be reported to Mr. Baohua Chen"); ECF No. [2663-12](#) 598:9-610:7 (ZHP employee testifying that he believes Mr. Chen was not informed of the July 27 email).)² Finally, the Special Master noted that there was "no testimony . . . that there was a failure to follow

² Plaintiffs have suggested that because the July 27, 2017 email was not found in Dr. Lin's custodial file at the time documents were produced in 2020-2021, ZHP must have "intended to conceal the email and any surrounding documents and communications." (ECF No. [2682](#), at 6 n.1.) This unsupported accusation was previously rejected by Judge Vanaskie. (See ECF No. [1573](#) 43:21-24.) And while Plaintiffs have also suggested that ZHP is withholding the "native" version of the July 27, 2017 email, ZHP only located a PDF version of the document.

litigation hold advice,” nor “evidence of the loss of any particular data,” including with regard to the July 27, 2017 email.³ (See ECF No. [1753](#), at 4.) For that reason, among others, the Special Master denied Plaintiffs’ motion to compel ZHP to continue looking for additional versions of the document. (*Id.*)

D. Special Master’s Ruling And Sanctions

The Special Master’s Order on Plaintiffs’ motion for sanctions (SMO 98 (ECF No. [2715](#))) was issued in May 2024, *more than two years* after briefing on the motion was completed by the parties. In that order, the Special Master adopted Plaintiffs’ argument that ZHP did not do enough to secure authorization for Mr. Chen to travel for his deposition and therefore violated SMO 28, as well as Plaintiffs’ assertion (unsupported by any facts) that Mr. Chen or ZHP could have done something to force the Chinese government to grant Mr. Chen’s travel permit application. In particular, the Court faulted Mr. Chen and ZHP for not expressly stating in the application that “Mr. Chen [had been] ordered by a federal court in the United States to appear for a deposition.” (SMO 98, at 19.) The Special Master also accepted that “ZHP ha[d] not shown that it attempted to appeal the denial [of Mr. Chen’s travel permit] via more formal measures,” which the Special Master failed to identify. (*Id.* at 20.)

³ The Special Master also noted that ZHP had “provided a credible explanation for [a] date-created anomaly on the July 27, 2017 email” given it was located in data recovered from a damaged hard drive. (ECF No. [1753](#), at 4.)

The Special Master also found that ZHP failed to comply with SMO 54, stating that while “ZHP has produced additional documents . . . at risk of prosecution under the [Chinese government’s] Data Security Law, these documents do not contain the breadth of information Plaintiffs are due.” (SMO 98, at 24.) But ZHP certified in 2022 that it had produced all the documents and information that it had for the four categories of documents at issue in SMO 54, including those from Ms. Kong’s files. (*See generally* Bernardo Cert.)

On July 22, the Special Master issued SMO 100, in which he concluded that two documents “remain[ed] outstanding: (1) “the native file and metadata” for the July 27 email; and (2) “the native files and any [additional] drafts of an internal” irbesartan report referenced in the email. (There is no dispute that a PDF of the email and a draft of the irbesartan report have been produced.)

SMO 100 authorized two nominally “permissive” adverse inference instructions regarding the Chen deposition and allegedly missing documents. The first one would instruct jurors that:

[i]f you find that defendants could have produced Mr. Chen for his deposition . . . you are permitted, but not required, to infer that . . . Mr. Chen’s deposition testimony would have been unfavorable to defendants. Specifically, you are permitted to infer that Mr. Chen’s deposition testimony would have included information about ZHP’s knowledge of the nitrosamine contamination of ZHP’s Valsartan [and] that information would have been unfavorable to ZHP.

(SMO 100, at 11.)

The second instruction states that:

ZHP failed to produce relevant documents that it was ordered to produce in this case. Specifically, ZHP was ordered to produce the native form of the July 27, 2017 email written by Jinsheng Lin. The July 27, 2017 email references ZHP's discussion of a problem presented by the finding of another nitrosamine impurity in Irbesartan, a similar drug manufactured by ZHP with a process similar to the process used to manufacture Valsartan. . . . The native form of these documents and their included metadata would have provided Plaintiffs information about when the document was written, when it was sent, who it was forwarded to and when, and other relevant information. . . .

If you find that ZHP could have produced these documents and their metadata, and that the evidence was within their control, and that the documents and metadata would have been relevant in deciding disputed facts in this case, you are permitted, but not required, to infer that the evidence would have been unfavorable to ZHP.

(*Id.* at 12.)

In addition to authorizing the aforementioned “adverse inference” instructions, the Special Master also approved Plaintiffs’ request for an award of attorneys’ fees of \$309,130.00 and an award of expenses of \$41,399.20. (*Id.* at 15.) According to the Special Master, Plaintiffs’ submission regarding the individual attorney rates and the number of hours spent in moving for sanctions was “reasonable.” (*Id.* at 15-16.)

ARGUMENT

This Court’s review of decisions issued by the Special Master is governed by Rule 53. Fed. R. Civ. P. 53(f)(3)-(4). Objections to the Special Master’s findings of fact and conclusions of law are subject to de novo review, unless the parties stipulate otherwise, which they have not done here. *See, e.g., Lawson v. Praxair,*

Inc., No. 16-2435(BRM)(DEA), 2023 U.S. Dist. LEXIS 198253, at *15-17 (D.N.J. Apr. 28, 2023) (reversing discovery ruling by special master and stressing that the court is “obliged to review issues *de novo*”). (*See, e.g.*, ECF No. [1994](#), at 5 (applying *de novo* standard of review to order on motion to amend answer to complaint).) “The phrase ‘*de novo* determination’ . . . means an independent determination of a controversy that accords no deference to any prior resolution of the same controversy.” *Valeant Pharms. Int’l, Inc. v. AIG Ins. Co.*, No. 18-493 (MAS)(LHG), 2020 U.S. Dist. LEXIS 244479, at *14-15 (D.N.J. Dec. 30, 2020) (citation omitted).

The Court should sustain ZHP’s objections and reverse the entry of sanctions because: (1) ZHP did not engage in any sanctionable conduct; and (2) the imposition of two adverse inferences is contrary to law and disproportionate to the alleged violations.

I. ZHP DID NOT ENGAGE IN SANCTIONABLE CONDUCT.

ZHP undertook reasonable, good-faith efforts to comply with SMO 28 and has produced all existing responsive, non-privileged documents under SMO 54. As a result, ZHP did not engage in conduct warranting sanctions.

A. ZHP Acted In Good Faith And With Reasonable Diligence To Secure Mr. Chen’s Presence For His Deposition.

ZHP should not be sanctioned for the Chinese government’s refusal to allow Mr. Chen to travel outside mainland China for a deposition.

The Supreme Court has made it clear that a party’s “*inability* to comply” with

discovery orders “because of foreign law” is “a weighty excuse for nonproduction, and this excuse is not weakened because the laws preventing compliance are those of a foreign sovereign.” *Societe Internationale*, 357 U.S. at 211-12 (emphasis added). Indeed, a district court “abuse[s] its discretion” in imposing sanctions for purported discovery violations where the foreign party has acted “in the best of faith” by, for example, requesting that the foreign government permit it to comply with a local discovery order. *See In re Westinghouse Elec. Corp. Uranium Conts. Litig.*, 563 F.2d 992, 996-98 (10th Cir. 1977); *accord Societe Internationale*, 357 U.S. at 208 (reversing imposition of sanctions where party did not collude with Swiss authorities to “block inspection” of the records, “and had in good faith made diligent efforts to execute the production order” by attempting to secure a waiver from the foreign government); *see also Lasky v. Cont'l Prods. Corp.*, 569 F. Supp. 1227, 1228-29 (E.D. Pa. 1983) (a court considering whether to impose any sanctions “must weigh considerations of international comity”).

In *Westinghouse*, the district court denied non-party Rio Algom’s motion to quash, rejecting its argument that producing its Canadian-based President for a deposition and related documents relevant to a party’s defense would violate Canadian Uranium Information Security Regulations. *Westinghouse*, 563 F.2d at 994-95. After unsuccessful efforts by the defendant to convince the Canadian Supreme Court to permit the production, Rio Algom subsequently requested the

consent of the Canadian government to release the company’s records so that it could comply with the discovery order. *See id.* at 995. When the Canadian government rejected that request (rendering compliance with the discovery order impossible under foreign law), the district court held Rio Algom in contempt and imposed a \$10,000 monetary penalty on it for each day it failed to comply. *See id.* The U.S. Court of Appeals for the Tenth Circuit reversed, reasoning that “the fact of foreign illegality” “prevent[ed] the imposition of sanctions” because Rio Algom “made diligent effort to produce materials not subject to the Canadian regulation” and “sought a waiver from the Canadian authorities.” *Id.* at 997-98. In so reasoning, the Tenth Circuit rejected the notion that “the timing” of the request (made after the entry of the discovery order) demonstrated a “lack of good faith” because “[t]he letter speaks for itself.” *Id.* at 998. Similarly, the Tenth Circuit rejected the unsupported “suggestion by Westinghouse” that Rio Algom somehow “caused the non[-]disclosure regulation to be promulgated in Canada in order to cover up for its activities or that Rio Algom and the Canadian government acted in collusion.” *Id.*

ZHP acted more diligently here. Even while ZHP’s motion to quash the deposition of Mr. Chen was pending—and despite zero efforts by Plaintiffs to secure the discovery through foreign channels (e.g., the Hague Convention)⁴—ZHP

⁴ The Special Master noted that “resort to the Hague Convention protocols” is not a prerequisite to obtaining foreign discovery. (SMO 98, at 15.) That, however, (cont’d)

initiated the process of obtaining the Chinese government’s permission for Mr. Chen to travel out of mainland China for his deposition. (*See* Lu Decl. ¶ 3.) Nonetheless, in late October, ZHP was informed that the Taizhou Exit-Entry Administration of the Public Security Bureau and the Taizhou Federation of Industry and Commerce would not grant Mr. Chen’s request. (*Id.* ¶¶ 7, 10.) Even after the two agencies denied Mr. Chen’s travel permit, ZHP continued to work with the Chinese authorities to determine whether the government’s decision could be reversed or modified. (*See* ECF No. [1673](#), at 1-2; *see also* Lu Decl. ¶ 11.) Although these efforts proved unsuccessful, they demonstrate ZHP’s diligence and good faith in attempting to facilitate Mr. Chen’s deposition and that any “*inability* to comply” with Judge Kugler’s order resulted from the actions of a foreign sovereign based on “foreign law.” *Westinghouse*, 563 F.2d at 997 (emphasis added) (quoting *Societe Internationale*, 357 U.S. at 212).

The Special Master nonetheless reasoned that ZHP’s efforts were inadequate because it did not undertake every conceivable step to persuade the Chinese government to grant Mr. Chen’s travel permit. (*See* SMO 98, at 19.) This reasoning

is a separate question from whether the requesting party’s failure to even attempt such procedures bears on the propriety of *sanctions*, which the Special Master previously recognized it does. (*See* ECF No. [1828](#) 10:1-3 (“And, yes, there is this other matter, other route of a – the route under the Hague [C]onvention, and that might preclude imposition of sanctions.”).)

fails both as a matter of law and fact.

First, even if SMO 100 were correct as a factual matter (which it is not), the applicable standard is whether ZHP acted in “good faith”—not whether it exhausted every possibility. *See Westinghouse*, 563 F.2d at 998. The handful of cases cited by the Special Master purportedly “addressing similar circumstances” are not to the contrary. (SMO 100, at 7.) For example, in *Giorgi Global Holdings, Inc. v. Smulski*, No. 17-4416, 2022 WL 4389523, at *4 (E.D. Pa. Sept. 22, 2022), the plaintiffs alleged that the defendant father and son “hid and laundered” money in foreign bank accounts. *Id.* at *1. Although the son was told by the foreign banks that he could produce key records from the accounts as long as he was the father’s heir, “he **rejected** his status as [the father’s] heir,” meaning that he “created the impediment that prevent[ed] him from producing the relevant bank records.” *Id.* at *6 (emphasis added). Similarly, in *Chevron Corp. v. Donziger*, 296 F.R.D. 168 (S.D.N.Y. 2013), the court made clear that “[w]here foreign law prevents production of documents, good faith may be demonstrated where a party seeks a waiver of foreign law, attempts to obtain the documents from other sources, or produces the documents in question to the extent they are not protected by foreign law.” *Id.* at 216-17 (citations omitted). It was only because the “[d]efendants did **none** of these things” that they were sanctioned. *Id.* (emphasis added). And in *Linde v. Arab Bank, PLC*, 269 F.R.D. 186 (E.D.N.Y. 2010), the defendants’ letters requesting permission from

foreign banking authorities to disclose confidential information “were calculated to fail” because they “mischaracterize[d] the status of the lawsuit,” “false[ly]” stating that the lawsuit had no “basis in reality or in the law” even though it had survived a motion to dismiss. *Id.* at 199 (citation omitted).

Although the Special Master also reasoned that a Delaware Chancery Court ruling previously cited by Judge Kugler supports the imposition of sanctions under these circumstances, that case is inapposite. (See SMO 100, at 8-9 (citing *In re Activision Blizzard, Inc.*, 86 A.3d 531 (Del. Ch. Ct. 2014)).) There, the court merely granted a motion to compel discovery and ordered the defendants to “make a good faith effort to secure permission from French authorities for a commissioner to oversee the taking of a deposition in France by plaintiff’s counsel.” *Id.* at 552. Because that is exactly what ZHP has done here, the Special Master’s authorities only confirm that ZHP’s conduct with regard to Mr. Chen does not warrant the imposition of any sanctions.⁵

⁵ The cases cited in SMO 98 similarly hold that a corporate defendant in a foreign country cannot avoid sanctions by simply “refus[ing] to take” any steps to comply with a discovery order in the U.S. (e.g., requesting that the foreign government permit the action), *Estate of Boyles v. Gree USA, Inc.*, No. 1:20-CV-276, 2021 WL 3292727, at *5, *7 (M.D.N.C. Aug. 2, 2021) (cited in SMO 98, at 17), or “prompt[ing]” the foreign government decision that “prevent[s]” compliance with the discovery order in the first place. *See Egyptian Chamois Co. v. Evergreen Marine Corp.*, No. CV 99-5080, 2001 WL 1737458, at *6 (C.D. Cal. Jan. 25, 2001) (cited in SMO 98, at 17) (imposing sanctions on plaintiff for failing to make its

(cont’d)

Second, ZHP objects to the Special Master’s finding that it did not undertake “all reasonable” steps to comply with the Court’s order for all the reasons set forth in ZHP’s prior Objections to SMO 98 (ECF [2738-1](#)), incorporated herein.

As explained in more detail in those Objections, the Special Master adopted Plaintiffs’ argument that “Mr. Chen’s visa application did not reflect the importance of Mr. Chen’s deposition in this litigation” because it did not specify that his appearance had been “ordered by a federal court in the United States.” (SMO 98, at 19.) But as ZHP and its expert explained, any such indication would have drawn even greater “scrutiny,” since the Chinese government is generally suspicious of American discovery demands made outside the Hague Convention. (deLisle Decl. ¶¶ 25, 29.) SMO 98 also faulted ZHP for not “seeking the help of a third-party organization specializing in assisting travelers in obtaining permits or gathering supporting documents to appeal the denial” (SMO 98, at 20; *see also id.* at 18), but neither Plaintiffs nor the Special Master identified any such third-party organization, and ZHP is not aware that one exists. Next, the Special Master took issue with ZHP’s failure to “appeal” the Chinese government’s decision. (*Id.* at 20.) But ZHP detailed the steps it took to engage in “further discussions with . . . Taizhou Federation of Industry and Commerce to determine if the restriction on Mr. Chen’s

officer available for a deposition where the officer’s “conduct prompted the travel ban and thereby prevented him from traveling to California”).

travel could be lifted or modified.” (*Id.* at 19-20 (quoting Lu Decl. ¶ 11).) And finally, the Special Master faulted ZHP for failing to “express its concerns regarding Mr. Chen’s ability to obtain a travel permit earlier in this proceeding [or] suggest alternative discovery tools.” (*Id.* at 20.) But ZHP’s counsel long ago expressed to the Court that the Chinese government was unlikely to allow Mr. Chen to travel for a deposition (*see* ECF No. [579](#) 12:3-6; ECF No. [1673](#), at 1-2; ECF No. [1386-1](#), at 9 n.6), and offered to have him answer written questions as an alternative (*see* ECF No. [1900](#), at 21 n.9). Plaintiffs’ counsel was not interested in that alternative.

During the recent status conference, the Court stated that “the big question I have is . . . what have you done about it lately?” (July 23, 2024 Hr’g Tr. 153:25-154:1.) ZHP understood the Court to be suggesting that ZHP should have re-filed an application for Mr. Chen to obtain a travel permit in the interceding years since his application was denied. However, in order to file a new application to leave the country, Mr. Chen (who has not left mainland China since the application denial) would need to identify a new event/reason for his travel. If the Court enters an order instructing Mr. Chen to be in a particular place at a specified time with an identified reason, he would be able to submit a new application and it would be processed. ZHP would, of course, act in good faith to submit such an application as soon as possible.

B. ZHP Produced The Documents That The Special Master Found Remain Outstanding.

The Special Master’s second ground for imposing sanctions is ZHP’s supposed non-compliance with SMO 54, which required the production of documents from the following four categories: (1) the custodial file of Mr. Chen’s chief of staff, Ms. Kong; (2) an investigative report regarding alleged contamination of irbesartan; (3) all documents referencing “TC-201729,” the project name for a lab-scale study of irbesartan; and (4) all documents relating to the batch testing for nitrosamines referenced in PRINSTON0075797. (SMO 98, at 5.) This basis is even more erroneous than the first because ZHP produced all non-privileged documents in its possession that fall within each of these categories more than a year and a half ago. (*See, e.g.*, Bernardo Cert. ¶ 3 (“ZHP conducted reasonable and duly diligent searches to identify documents responsive to SMO 54 and produced responsive, non-privileged documents identified.”).) As a result, ZHP has complied with the document-related discovery order, effectively mooting this portion of Plaintiffs’ motion. *See, e.g.*, *Castellani v. City of Atlantic City*, No. 13-5848 (JBS/AMD), 2016 WL 7131576, at *5 (D.N.J. June 30, 2016) (sanctions “not warranted” where defendant made a production, “albeit after the deadline imposed by the [c]ourt’s . . . [o]rder,” in a form that defendant believed to be sufficient); *Givaudan Fragrances Corp. v. Krivda*, No. 08-4409 (PGS), 2012 WL 12917268, at *16 (D.N.J. May 8, 2012) (denying plaintiffs’ motion for sanctions as “moot” where plaintiffs conceded

that by the date of the sanctions hearing, defendants' production was adequate).

The Special Master nonetheless insisted that certain discovery "remain[s] outstanding"—specifically, the native file and metadata for the July 2017 email regarding irbesartan and the native files and any additional drafts of an internal report regarding the evaluation of a proposed irbesartan manufacturing change at issue in the July 2017 email. (SMO 100, at 3.) This ruling is contrary to the certification signed by ZHP's counsel stating that there are **no** additional responsive documents within ZHP's possession. (*See* Bernardo Cert.) *See, e.g., Cache La Poudre Feeds, LLC v. Land O'Lakes, Inc.*, 244 F.R.D. 614, 631 (D. Colo. 2007) (denying plaintiff's motion for sanctions for failing to produce certain documents; "[o]n the available record, the court must accept, at face value, [d]efendants' representations that they did not keep" such documents); *Prokosch v. Catalina Lighting, Inc.*, 193 F.R.D. 633, 637 (D. Minn. 2000) (denying motion for sanctions based on purported failure to produce documents because a court "must accept, at face value, a party's representation that it has fully produced all materials that are discoverable" regardless of whether explanation is implausible) (citation omitted).

Importantly, the fact that these materials do not exist makes perfect sense. The July 2017 email was only found after exhaustive searches and after data had been recovered from a damaged hard drive. (ECF No. [1753](#), at 4.) Further, because ZHP was only able to find the July 2017 email in PDF format, there was no metadata

to produce with regard to that document. (*See* Bernardo Cert. ¶ 9.) Similarly, it is hardly surprising that ZHP does not have additional documents related to TC-201729—the investigation at issue in the July 2017 email—because it related to a different drug and a proposed manufacturing process change that ZHP ultimately chose **not** to adopt. Accordingly, there is no basis for disregarding ZHP’s counsel’s representations regarding ZHP’s careful and repeated reviews of its files.

In sum, neither of the two bases underlying the Special Master’s ruling is a legal predicate for the imposition of sanctions. For this reason alone, the Court should reverse the Special Master’s ruling.

II. THE SEVERE SANCTIONS APPROVED BY THE SPECIAL MASTER ARE DISPROPORTIONATE AND UNCONNECTED TO THE ALLEGED VIOLATIONS.

Even if there were a valid basis to conclude that ZHP engaged in sanctionable conduct, the extreme sanctions proposed by the Special Master would be highly improper. While the Special Master went out of his way to distinguish the “adverse inferences” from the “death penalty” sanctions of striking ZHP’s answer and deeming certain allegations admitted (SMO 100, at 1-2), that misapprehends the real import of the instructions. Regardless of how they are labeled, the practical effect of the instructions is to invite jurors to assume that ZHP knew of (and actively hid) the presence of nitrosamines at the time the July 27, 2017 email about irbesartan was written. The Court should reject such a result because it: (1) is disproportionate to

the wrongdoing alleged and therefore not a “just” punishment; and (2) lacks the required connection to the discovery at issue.

First, the adverse inference instructions are disproportionate. As courts have recognized, a sanction that essentially robs a party of asserting or contesting a required element of a claim at issue is akin to the extreme sanction of a default judgment. *See FS2 Cap. Partners, LLC v. Church*, No. 14-4933, 2015 WL 246339, at *4-5 (E.D. Pa. Jan. 16, 2015) (declining to issue court order stating that an element of the plaintiff’s claim was met as a sanction for the defendant’s failure to sit for a deposition because such a finding would be “equivalent to default judgment”). For this reason, courts in the Third Circuit and elsewhere routinely reject the imposition of adverse inferences as discovery sanctions where they would have the practical effect of instructing the jury that an element of the claims against a defendant has been established. *See, e.g., Gertcher v. Therrian*, No. 2:20-cv-240, 2022 WL 842655, at *6 (W.D. Mich. Mar. 22, 2022) (denying motion for adverse inference concerning the content of destroyed evidence because “a mandatory adverse inference instruction would have much the same effect as a default judgment”); *In re Lands’ End Leasing, Inc.*, 220 B.R. 226, 233 (Bankr. D.N.J. 1998) (refusing to issue sanctions order deeming the facts in the complaint established based on party’s refusal to appropriately respond to sanctions order; “the Third Circuit . . . guard[s] the right to one’s day in court so zealously” that failing to adhere to a sanction order

is not “sufficiently egregious to forfeit that right”).

The sanctions entered by the Special Master would do precisely that by suggesting to jurors that a deposition of Mr. Chen would have credited Plaintiffs’ theory of the case—i.e., that ZHP hid information regarding the potential for nitrosamine formation in Valsartan in 2017. While the instructions are technically couched in permissive terms—i.e., that jurors “are permitted to infer” rather than required to infer—jurors are likely to interpret it as a strong recommendation by the Court that they accept Plaintiffs’ theory that ZHP was aware its valsartan API contained nitrosamines at least a year before the product recall and that ZHP and its President engaged in deceptive conduct by hiding that information from valsartan users, consumers and third-party payors. Such a sanction is not appropriate under Third Circuit law, especially absent any evidence of bad faith on the part of ZHP, as discussed extensively above.⁶

Second, the Special Master’s proposed adverse inferences that “Mr. Chen’s

⁶ In a footnote, the Special Master reasoned that “[o]rdering the permissive adverse inference, which ZHP may rebut through available evidence already produced in this case, does not create a substantive concern” like the one at issue in *Clientron Corp. v. Devon IT, Inc.*, 894 F.3d 568, 581 (3d Cir. 2018). (SMO 100, at 6 n.2.) In *Clientron*, the sanctioned party violated due process by “circumvent[ing] the substantive law.” *Id.* at 581. Similar logic applies here because the effect of the entered instructions would be to effectively abrogate Plaintiffs’ burden of proof with regard to the critical knowledge and scienter elements of their state-law causes of action.

deposition would have been unfavorable to defendants”; that the purportedly missing “metadata” “would have been unfavorable to ZHP”; and that they would have “included information about ZHP’s knowledge” are especially inappropriate because they are not factually or logically linked to the discovery that Plaintiffs are purportedly missing.

It is well recognized that “[b]efore drawing an adverse inference, courts typically require some showing, by circumstantial evidence or otherwise, of the content of the destroyed evidence,” as well as a showing that a “reasonable jury could infer that the [missing discovery] contained” the information the jury is instructed to infer. *Emerson v. Wetherill*, No. CIV. 92-4082, 1994 WL 249769, at *3 (E.D. Pa. June 1, 1994) (rejecting adverse inference that a party “committed prior acts of misconduct” as a sanction for the loss of documents because “no reasonable jury could infer that the destroyed documents contained such information”); *Consol. Aluminum Corp. v. Alcoa, Inc.*, 244 F.R.D. 335, 346-47 (M.D. La. 2006) (rejecting adverse inference sanction because, “before an adverse inference may be drawn, there must be some showing that there is in fact a nexus between the proposed inference and the information contained in the lost evidence,” and there was no “extrinsic evidence establishing that the lost evidence would have supported” the proposed adverse inferences).

For example, in *Sovulj v. United States*, No. 98 CV 5550FBRML, 2005 WL

2290495, at *5 (E.D.N.Y. Sept. 20, 2005), *on reconsideration*, No. 98-CV-5550 (FB), 2008 WL 11449125 (E.D.N.Y. May 13, 2008), the court refused to issue an adverse inference that an x-ray film of the plaintiff's deceased husband's lung, which was not produced despite several requests, would have shown a tumor. *Id.* at *3, *6. According to the court, the purpose of an adverse inference is to "restor[e] the prejudiced party to the same position he would have been in absent the wrongful destruction of evidence by the opposing party." *Id.* at *5 (alteration in original) (citation omitted). The court held that the adverse inference sought "would not have the effect of restoring the plaintiff to her position absent the destruction of the x-ray, but rather would prejudice the defendant by allowing plaintiff to profit from the destruction of the x-ray when no evidence has been presented to support such an inference of its contents." *Id.*

The adverse inferences entered by the Special Master would similarly "not have the effect of restoring the plaintiff[s]" to the position they would have been in if ZHP's President, Mr. Chen, could have been deposed or if the metadata related to the July 2017 email existed. As for Plaintiffs' inability to depose ZHP's president, there is no evidence that Mr. Chen, who was not an addressee on the July 27, 2017 email, was aware of the irbesartan email or internal irbesartan report in June 2017, much less that he had "unfavorable" "knowledge of nitrosamine contamination." (SMO 100, at 11.) To the contrary, the testimony from ZHP employees suggests he

would not have been involved in science-related issues of this kind. (See, e.g., ECF No. [2663-27](#) at Ex. 1 96:5-21; ECF No. [2663-12](#) 598:9-610:7.) And even if there were evidence of Mr. Chen’s awareness, the issue at that stage related to *irbesartan*, which has nothing to do with the TPP *valsartan* trial at which these sanctions are to be imposed. Moreover, Plaintiffs have the July 27, 2017 email and irbesartan investigation report in their possession, along with deposition testimony about them from multiple ZHP witnesses. And if Plaintiffs believed they needed testimony from Mr. Chen to present their arguments to the jury, they could have pursued a written deposition; instead, they declined to do so, possibly in hopes they could obtain a windfall through a sanctions motion.

The instruction related to so-called “withheld documents” likewise cannot be justified. This instruction is predicated on the finding that ZHP supposedly failed to produce “the native file and metadata regarding the July 27, 2017 email, and the native files and any drafts of the internal Irbesartan Report regarding the investigation.” (SMO 100, at 10.) But, as explained in detail above, ZHP’s counsel searched for those documents and issued a certification in 2022 confirming that, to the extent such documents existed, they had been produced. Thus, the record demonstrates that there is no “missing” evidence pertaining to the July 27, 2017 email in ZHP’s control.

In any event, Plaintiffs already have all of the information that any metadata

could possibly reveal related to the July 2017 email and irbesartan investigation. Thus, even a permissive adverse inference would provide them a substantial windfall rather than a level playing field. In particular, although the instruction claims that additional data “would have provided Plaintiffs information about when the document was written, when it was sent, who it was forwarded to, and when” (SMO 100, at 12), Plaintiffs already know who wrote the email, when it was written and who received it. Similarly, all of the Excel documents that were located in connection with the irbesartan investigation were produced with metadata. Neither Plaintiffs nor the Special Master has identified what additional metadata or report drafts could possibly show.

In short, instructing jurors that they “are permitted to infer” that any missing evidence would have provided “unfavorable information” or suggested “ZHP’s knowledge of the nitrosamine contamination” has no evidentiary support.

For this reason, too, the Special Master’s “adverse inference” sanctions should be overturned.

CONCLUSION

For the foregoing reasons, the Court should sustain ZHP’s objections to the Special Master’s Order, reverse the Special Master’s rulings in SMO 100, and deny Plaintiffs’ motion for Rule 37 sanctions.

Dated: August 2, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 2, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson

Jessica Davidson (NY Bar No. 6034748)